REMARKS

The Office Action mailed on July 9, 2007, has been reviewed, and the comments of the PTO have been considered. Prior to entry of this paper, claims 1-58 and 60-140 were pending, with claims 10-35, 54-105, 119, 120, 123-126, and 129-136 withdrawn. Applicant presently cancels no claims and adds claims 141-144. Upon entry of this paper, therefore, claims 1-58 and 60-144 will be pending.

Applicant respectfully submits that the present application is in condition for allowance for at least the reasons that follow.

Request for Interview

Applicant respectfully requests that in the event that the PTO does not agree that the claims are in condition for allowance, Examiner Sasan extend the courtesy of an interview to Applicants' representative prior to the generation of any next office action.

Specifically, Applicant requests that Examiner Sasan contact his representative, Martin Cosenza, at (202) 295-4747, to schedule an in-person interview to this application, prior to any next office action that is not a notice of allowance / Quayle action.

Applicant hereby submits a Request for Interview form in Appendix I.

(A) Rejections Under 35 U.S.C. § 102

Claims 1, 5-7, 36, 41-43, 45-47, 49, 122 and 127 stand rejected for alleged anticipation by "PCT '676"(WO 01/03676). Applicant notes, however, that a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131. In this vein, Section 103 further states that the claimed subject matter must be "*identically* disclosed or described" by the prior art reference (emphasis added). Applicant submits that PCT '676 does not

describe each and every element of any of the independent claims at issue and, hence, that this rejection under Section 102 should be withdrawn as to those claims.

More specifically, claim 1 recites a multi-compartment capsule, comprising a first receiving chamber comprising at least one ingredient having a first physical state, wherein said ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral, and second receiving chamber comprising at least one ingredient having a second physical state, where the ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral.[1] That is, for claim 1 to be anticipated, a prior art reference must teach a multi-compartment capsule as claimed, that includes a nutraceutical, a vitamin and/or a dietary supplement in both capsules.

The Office Action asserts that PCT '676 teaches each element of claim 1. Yet, in detailing the grounds for rejection of claim 1, the Office Action does not address the feature regarding a nutraceutical, a vitamin and/or a dietary supplement being present in both compartments. Indeed, on pages 5-6, where the Office Action details the rejection of claim 1, the Office Action identifies an alleged teaching of "two separate pharmaceutical preparations": "dextromethorphan liquid in one chamber and chlorpheniramine powder in the second chamber." Since these are not nutraceuticals, vitamins or dietary supplements, claim 1 cannot be deemed anticipated by PCT '676.

Independent claim 36 recites a multi-compartment capsule, comprising a first receiving chamber comprising at least one active ingredient having a first physical state, and a second receiving chamber comprising at least one active ingredient having a second physical state, wherein said first physical state of said active ingredient of said first receiving chamber ***is different*** from said second physical state of said active ingredient of said second receiving chamber. As a patentably distinguishing feature from PCT '676, claim 1 further recites that "said active ingredient of said first receiving chamber is different from said active ingredient

1 Claim 1 further recites that said first physical state of said ingredient of said first receiving chamber is different from said second physical state of said ingredient of said second receiving chamber, and that said ingredient of said first receiving chamber is different from said ingredient of said second receiving chamber.

of said second receiving chamber ***and not present in said second receiving chamber***" (emphasis added).

PCT '676 does not teach any embodiment that falls within claim 36. In particular, the Office Action points to no teaching in PCT '676 that the active ingredients in one chamber are *absent* from the other chamber. Rather, the Office Action alludes to a disclosed embodiment in which "dextromethorphan liquid [is] in one chamber and chlorpheniramine powder [is] in the second chamber" (page 7). This disclosure does not teach the presently recited *segregation* feature as such, however. That is, PCT '676 fails to require that the two ingredients -- "dextromethorphan liquid" and "chlorpheniramine powder" -- are not present in one chamber.

By analogy, one may say that a first car has a CD player as part of the stereo system, and one may say that a second car has a tape deck as part of the stereo system. This does not mean, however, that the first car lacks a tape deck and/or that the second car lacks a CD player. By the same token, the segregation-of-ingredients feature is not present in PCT '676; hence, the reference cannot anticipate claim 36.

(B) Claim Rejections Under 35 U.S.C. §103(a)

Claims 2, 8, 9, 38, 44, 48, 50-53, 106-118, 121, 128 and 137-140 stand rejected over PCT '676 in view of Zimmer, U.S. Patent No. 5,310,555, while claims 3-4, 37 and 39 are rejected over the combination of PCT '676, Zimmer, and Rashid, U.S. Patent No. 5,750,143. Claim 40 is separately rejected in view of PCT '676 and Zimmer with Story, U.S. Patent No. 5,738,871.

In order to advance prosecution, and without prejudice or disclaimer, Applicant hereby eliminates the ultimate dependency of these claims on claims 1 and 36, respectively. The amended claims depend from new claims 141 and 142, respectively.

With the foregoing revisions, no pending claim is properly adjudged obvious, within the meaning of Section 103, over any combination the relies on PCT '676. Applicant elaborates on this position in the commentary below.

* * * * *

Claims 141 and 142 parallel claims 1 and 36, respectively, but they further recite that the multi-compartment capsule is a "hard shell capsule." The original specification amply supports for this qualification, as discussed in the next section.

PCT '676 does not suggest this feature, and the skilled artisan would not have found it obvious to modify PCT '676 to arrive at the hard shell capsule, as claimed. Evidencing the latter fact is the accompanying Rule 132 declaration of Carey Bottom (Appendix II hereto).

As attested in paragraph 3 of his declaration, Dr. Bottom was a President and a member of the Board of Directors of BioProgress Technology, Inc., the assignee of PCT '676. Knowing the named PCT' 676 inventors personally and having discussed the technology with them in detail (see paragraph 4), Dr. Bottom was privy to their thinking about the technology.

Thus, Dr. Bottom has unique insight into facts relating to the technology detailed in PCT '676. Furthermore, BioProgress was well-positioned and motivated to evaluate possible modifications to the PCT '676 technology (see paragraphs 22 and 23). Accordingly, the Bottom Declaration is highly probative evidence of the non-obviousness, in view of PCT '676, of pending claims that recite a hard shell capsule.

I. <u>The ordinary artisan would not have sought to apply the teachings of PCT '676 to a hard shell capsule according to the claims</u>

Paragraphs 12-23 of the Bottom Declaration attest to facts demonstrating that the skilled artisan would not have found it obvious to modify PCT '676 to arrive at the subject matter of claims 141 and 142. Specifically, the declaration states how BioProgress developed a unique, "pre-dried film," which was "[c]ritical to the . . . septum concept," the septum being central in PCT '676 to the disclosure of a bi-phasic, multi-ingredient, multi compartment capsule (paragraphs 13, 15, and 17). Dr. Bottom details that the drug delivery community was aware that the septum of PCT '676 is formed from this pre-dried film (paragraph 18), and that it was common knowledge that capsules made from the pre-dried film, as developed by BioProgress, were not hard shell capsules (paragraph 19).

Dr. Bottom attests that, as "of February, 2003, the view was widespread, within and outside of BioProgress, that the hard shell capsule format was unsuited and inadequate for

producing a capsule with a septum, in accordance with PCT '676" (paragraph 20). He also testifies that, despite motivation at the time to develop new drug encapsulation systems, no one at BioProgress ever thought to modify the teachings of PCT '676 to accommodate use in a hard shell capsule, and that no one outside of BioProgress ever disclosed such a modification (see paragraphs 22 and 23).

In view of these facts, it is respectfully submitted that the PTO cannot substantiate an assertion that it would have been obvious for the ordinary artisan, in the February 2003 timeframe, to have modified the teachings of PCT '676 to obtain a hard shell capsule as claimed in claims 141 and 142, but there is more.

II. The artisan would have eschewed the unmodified teachings of PCT '676

Paragraphs 24-28 of the Bottom Declaration attest to facts showing why one or ordinary skill would not have sought out PCT '676 for modification to obtain a capsule as recited to claims 141 and 142.

Thus, paragraph 24 details how the above-discussed "pre-dried film" technology, which engendered the embodiments presented in PCT '676, presented difficulties in implementation that anyone would have encountered in attempting to practice the teachings of PCT '676. Indeed, Dr. Bottom attests in paragraph 25 that BioProgress, the originator of the technology, was unable to produce a capsule, characterized by bi-phasic ingredients, pursuant to those teachings. See also paragraphs 26-28 (difficulties associated with implementing PCT '676 would have militated against modifying PCT '676 in the manner posited by the PTO). For these reasons as well, therefore, claims 141 and 142 cannot be deemed obvious in view the prior art illustrated by PCT '676.

(C) Support for Claims 141 – 144 in Specification

Applicant has added claims 141-144. Support for these claims appears, among other places: in priority application Serial No. 10/368,951, at paragraph 0096 of the published version, No. 2003/0194428; in priority application Serial No. 10/369,244, at paragraph 0098 of the published version, No. 2003/0194429; in priority application Serial No. 10/369,247, at paragraph 0097 of the published version, No. 2003/0194430); and in priority application Serial No. 10/369,427, at paragraph 0099 of the published version, No. 2003/0194431 (in

each instance, detailing amounts of plasticizer that may be used in capsules of the invention). (See also, for example, Serial No. 10/368,951, at paragraph 0144 and 0145 of the published version, etc., detailing features of some embodiments of the present invention including shelf-life and stability.)

(D) Rejoinder of the Withdrawn Claims

Any withdrawn claims that depend from claims 141 or 142 should be rejoinder and allowed. This action would comport with PTO's indication that, "upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim." Office Action dated January 30, 2007, a page 8 (citing 37 CFR § 1.141 and MPEP § 809.02(a)).

The withdrawn independent claims likewise should be rejoined and allowed, based on the same reasons for allowance advanced above for claims 1 and 36. The method claims also should be rejoined and allowed, pursuant to *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995), and MPEP § 821.04 ("when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product").

CONCLUSION

Applicant submits that the present application is in condition for allowance, and an early indication to this effect is requested. Examiner Sasan is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, Applicant hereby petitions for such extension under 37 CFR §1.136 and authorizes payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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By _____

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